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Centers for Medicare and Medicaid Services

HCPCS Public Meeting Agenda for
JUNE 23, 2005
DURABLE MEDICAL EQUIPMENT (DME)

Please note that this agenda contains preliminary decisions and do not necessarily reflect what the final decisions will be. Preliminary decisions provide a basis for comment at public meetings. All coding changes, when finalized will be published by mid November on the CMS HCPCS website at www.cms.hhs.gov/medicare/hcpcs, and effective January 1, 2006 unless otherwise noted in the HCPCS Annual Update or on a Quarterly Update.

The agenda includes a summary of each HCPCS code application on the agenda. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

Each meeting day will begin at 9 a.m. and is scheduled to end at 5 p.m., E.S.T. However, because it is impossible to anticipate whether all presentations will fill their allotted time period (e.g. 15 minutes for Primary Speakers; or 5 minutes for "5-Minute Speakers"), we cannot commit specific items to specific time frames, and we can only estimate the amount of meeting time that will be needed. Meetings may end earlier than 5:00 p.m. Meeting participants should arrive early and plan on the meeting commencing promptly at 9:00 a.m., and speakers are asked to please arrive prepared and wait until it is their turn to speak.

Meeting Agenda Item #1
June 23, 2005
HCPCS Request #05.02

Background/Discussion:
Bill Niland of Vapotherm, Inc. submitted a request to establish a code for a high flow humidification system, trade name: Vapotherm 2000h. According to the requester, The Vapotherm 2000h is the only device available that can comfortably and adequately deliver breathing gas flows of up to 40 liters per minute directly to a nasal cannula, or other small-tube respiratory interfaces, without a supplemental air source. This system consists of the base driver unit and a series of accessories for single patient use in the patient's home. Vapotherm used membrane transfer technology to saturate a stream of air and/or oxygen to generate a high flow of warm and sterile vapor. High flow is indicated for numerous chronic lung diseases, acute respiratory insufficiency, apnea of prematurity, respiratory compromise where gas exchange in the respiratory tract needs improvement and where work of breathing needs to be reduced.

CMS HCPCS Workgroup Preliminary Decision: Use existing code E0550 humidifier, durable, glass or autoclavable plastic bottle type, for use with regulator or flowmeter.

Existing code E0550 is available for use by all payers, and adequately describes a category of humidifiers for use with a regulator or flowmeter which perform a function similar to the Vapotherm 2000h. The study provided with the application does not support a claim of therapeutic distinctions between the category of items described by E0550 and the Vapotherm 2000h. No insurer identified a national program operating need to distinguish the Vapotherm 2000h from other items coded at E0550 based on different pressures or efficiency. Code assignment is made by the insurer in whose jurisdiction a claim would be filed. For Medicare, use code E0550; use of miscellaneous codes to identify this product is inappropriate. For private insurance sector, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Meeting Agenda Item #2
June 23, 2005
HCPCS Request #05.120

Background/Discussion:
Ron Billingsley of Respironics, Inc. submitted a request assign a HCPCS code to the Prodose Adaptive Aerosol Delivery System and requests that the code descriptor state that the device is specifically for use with Ventavis. According to the requester, the Prodose AAD system represents a unique technology to deliver a predefined amount of aerosol to the patient's lungs. AAD was designed to minimize the variability of the delivered dose, to minimize the waste of aerosol to the environment and to improve the patients' adherence to their treatment and compliance with the user specification of the device. AAD systems adapt delivery of aerosol to the patient's breathing patterns, eliminating the greatest source of variability in drug delivery associated with conventional jet and ultrasonic nebulizers. The timing of the pulse of aerosol to be delivered to the patient is determined by the analysis of the breathing pattern. AAD systems analyze the pressure changes of the airflow of the first three breaths, to ascertain the correct starting point for aerosol delivery. It also provides the patient with feedback on how to effectively use the AAD system during the treatment, which improves adherence to treatment and compliance with device. Prodose uses the AAD disc to control drug delivery. The Prodose system consists of a compressor connected to a self-powered hand piece fitted with a liquid crystal display.

CMS HCPCS Workgroup Preliminary Decision: To establish a new "E" code.

E???? Controlled dose inhalation drug delivery system.

Medicare Payment:
This item falls under the capped rental DME payment category. The allowed rental payment amounts for this device will be based on the contractor's individual consideration of each claim until fee schedule amounts can be established for this new code.

Meeting Agenda Item #3
June 23, 2005
HCPCS Request #05.121

Background/Discussion:
Terry O'Brien of Omron Healthcare, Inc. submitted a request to have the NE-U22 Micro-Air vibrating mesh nebulizer reclassified from under current HCPCS code E0574 ULTRASONIC/ELECTRONIC AEROSOL GENERATOR WITH SMALL VOLUME NEBULIZER to E0571 AEROSOL COMPRESSOR, BATTERY POWERED, FOR USE WITH SMALL VOLUME NEBULIZER. According to the requester, NE-U22 is a small volume electronic nebulizer that operates on 2 "AA" batteries and has an AC power option. It produces a breathable aerosol by breaking solution medications into small aerosol particles that can be inhaled into the lungs. The nebulization takes place by forcing medication from the medication bottle through a mesh plate containing 6,000 holes. Nebulized medication then passes from the top of the mesh through either a mouthpiece or mask to the user, which is then inhaled into the lungs. NE-U22 is used by any patient who suffers from respiratory conditions that require medications that are delivered to the lungs. NE-U22 provides relief of airway disease and can be used in any setting provided that the patient has access to their medication and device.

CMS HCPCS Workgroup Preliminary Decision: To use existing code E0574 ultrasonic/electronic aerosol generator with small volume nebulizer.

Existing code E0574 adequately describes a category of nebulizers that perform a function similar to the item that is the subject of this request, and is available for use by all payers. Assignment of codes to individual products is made by the insurer in whose jurisdiction a claim if filed. For Mediccare, as long as the patient meets the criteria in medical policy, the product is paid for using the fee assigned to E0574. Based on its policy, Medicare may downcode based on medical necessity. The method of breaking up the solution is not an issue. The item is essentially AC powered, but can have batteries. It is not primarily battery powered. The battery is a back up to the AC power source. The setting of fees and reimbursement rates associated with codes is outside the jurisdiction of the code set maintainers. If you have a concern regarding the fee associated with E0574, please submit your inquiry directly to the insurer. For Medicare, please contact CMS' Inherent Reasonableness Authority. For private insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Meeting Agenda Item #4
June 23, 2005
HCPCS Request #05.122

Background/Discussion:

Beth Guevara of Respironics, Inc. submitted a request to establish a separate code for a therapy data management system for positive airway pressure devices, trade name: Respironics SleepLink™ Modem System and Encore® Pro SmartCard® Technology. The SleepLink and SmartCard are used with continuous positive airway pressure (CPAP) devices and bi-level respiratory devices. In addition, the SleepLink can be used with XPOD® oximetry device to provide oxygen saturation data. Both products are use by patients who are diagnosed with obstructive sleep apnea that utilize CPAP and bi-level technology in the treatment of their condition. Compliance and event monitoring information associated with the use of these devices is essential to the effective treatment of sleep-related conditions. The SleepLink and SmartCard are two technologies that provide efficient ways to monitor sleep therapy compliance and event data by offering in-depth information for analysis. SmartCard is a removable data recorder card that is installed into the side of a compatible PAP device. It can then be downloaded for review by the patient's physician or homecare provider through the use of Encore Data Management Software. SleepLink is a data recorder system like the Smartcard with the addition of a modem device that allows home care providers to transmit data for review and interpretation by the treating physician. The SleepLink allows the option to download compliance data only or compliance data and oximetry information simultaneously.

CMS HCPCS Workgroup Preliminary Decision: Use existing code A9900 miscellaneous DME supply, accessory, and/or service component of another HCPCS code.

This product was originally cleared for marketing as a component to a BiPAP and CPAP device, and is included in the code that describes the BiPAP or CPAP device. Appropriate code assignment is made by the insurer in whose jurisdiction the claim is filed. For Medicare, A9900 is the appropriate code. No insurer identified a national program operating need to alter the existing code set to describe this item. E1399 or other miscellaneous codes should not be used to identify this item on a Medicare claim.

Medicare Payment : There is no separate payment for this DME component since payment for all necessary components of DME is included in the payment for the DME (i.e., CPAP or respiratory assist device).

Meeting Agenda Item #5
June 23, 2005
HCPCS Request #05.123

Background/Discussion:
Martha Christian of the Princeton Reimbursement Group submitted a request to establish a code for auto or self-adjusting positive airway pressure devices (APAP), trade name: AutoSet Spirit System. According to the requester, AutoSet Spirit is a flow-based auto-adjusting respiratory device used in the treatment of Obstructive Sleep Apnea. It employs sophisticated sensors and microprocessors not present in standard CPAP machines. The device's unique mode of action allows the device to respond to these various parameters: flow limitation, snoring, hypopnea, complete obstruction or any combination of the aforementioned breathing patterns. AutoSet's mode of action delivers varying levels of pressures based on the detected sleep disordered breathing events and may change pressure on a breath-to-breath basis. This device is only used when the patient has failed on a standard CPAP.

CMS HCPCS Workgroup Preliminary Decision: To use existing code E0601 continuous airway pressure (CPAP) device.

An existing code E0601, adequately describes a category of items which are functionally similar to the item in this coding request. As stated in the National Coverage decision for CPAP, the device's clinical function is to prevent the collapse of the oropharyngeal walls and then obstruction of airflow during sleep, which occurs in obstructive sleep apnea. Although changes in operating technology may exist, there are no related changes in clinical function or patient outcome. Additionally, there are no significant therapeutic distinctions between the category of items described in this code and the item in the coding request. The evolutionary enhancements of AutoSet Spirit do not change its core function. Even with auto-adjustments (as opposed to mechanical adjustments), the product affects inspirational breath only, and its core function is to prevent obstructive sleep apnea, which makes it a CPAP device.

Isolation of a product from similar products in an existing HCPCS code category based on improved patient outcome, unique clinical indications or benefits for a specific subset of patients is a matter that should be considered in relation to the individual insurer' coverage policies. When substantiating clinical evidence becomes available, the appropriate mechanism for requesting to distinguish the AutoSet Spirit from other, similar products on the basis of difference in clinical function or patient outcome is to approach individual insurers for reconsideration of coverage and policy. For Medicare, such requests are submitted to CMS's Coverage and Analysis Group, along with required substantiating documentation. More information regarding their National Coverage Determination process can be found at http://www.cms.hhs.gov/coverage.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Meeting Agenda Item #6
June 23, 2005
HCPCS Request #05.124

Background/Discussion:
Nicholas Macmillan of DeVilbiss submitted a request to establish 2 codes A) 1 code for the modem and B) 1 code for the subscription fee of an electronic positive airway pressure monitoring device, trade name: eCompliance. According to the requester, eCompliance is an electronic compliance tracking system that is comprised of three elements: smart track modem, internet processing software and PAP device (CPAP, bilevel or AutoAdjust). eCompliance is a system that electronically monitors a patient's PAP usage and automatically notifies those responsible for therapeutic management, i.e. physician, sleep technologist, home medical equipment provider, of low usage. The system works with standard CPAP, bilevel and auto-adjusting devices. Objective and quantitative parameters monitored include daily hours of use, on/off data and pressure. The PAP device is set up in a patient's home. The SMLink 300 is connected to the PAP device and to the patient's telephone line. SMLink quietly calls the DeVilbiss IPS server during the night and transmits the previous day's information. The call frequency is the first 7 days and every 3 days thereafter. Patient PAP information is available via the secure, password protected IPS server, 24/7.

CMS HCPCS Workgroup Preliminary Decision: Use existing code A9900 miscellaneous DME supply, accessory, and/or service component of another HCPCS code.

This product was originally cleared for marketing as a component of a BiPAP and CPAP device, and is included in the code that describes the BiPAP or CPAP device. Appropriate code assignment is made by the insurer in whose jurisdiction the claim is filed. For Medicare, A9900 is the appropriate code. No insurer identified a national program operating need to alter the existing code set to describe this item. E1399 or other miscellaneous codes should not be used to identify this item on a Medicare claim. Inquires regarding the appropriateness of separately billing a CPT code for interpretation should be submitted directly to the insurer in whose jurisdiction a claim would be filed.

Medicare Payment: There is no separate payment for this DME component since payment for all necessary components of DME is included in the payment for the DME (i.e., CPAP or respiratory assist device).

Meeting Agenda Item #7
June 23, 2005
HCPCS Request #05.125

Background/Discussion:
Steve Moore of Fisher & Paykel Healthcare, Inc. submitted a request to establish a code for a CPAP system with heated CPAP delivery tubing, trade name: HC604JHU Integrated Humidified CPAP with ThermoSmart Heated CPAP tubing. According to the requester, the HC604JHU Integrated Humidified CPAP is a CPAP device with an inbuilt heated humidifier. It utilizes a proprietary algorithm and an internal power supply to provide the power to run a heated breathing circuit known as 900HC522 ThermoSmart heated CPAP delivery tubing. The HC604 and ThermoSmart tubing combine to deliver positive airway pressure with optimal humidity, condensation free to CPAP patients. ThermoSmart is used in the home for patients that require heated humidification with positive airway pressure therapy. This form of PAP is primarily prescribed to patients with Obstructive Sleep Apnea.

CMS HCPCS Workgroup Preliminary Decision: To establish a new code "A" code.

A???? Tubing with integrated heating element for use with positive airway pressure device.

Medicare Payment:
This item falls under the inexpensive or routinely purchased DME payment category. Fee schedule amounts are established by the DMERCs in accordance with CMS gap-filling instructions.

Meeting Agenda Item #8
June 23, 2005
HCPCS Request #05.126

Background/Discussion:
Steve Moore of Fisher & Paykel submitted a request to establish a code for a heated humidification system, trade name: MR850 Heated Humidification System. According to the requester, the MR850 heated humidification system is stand-alone "durable medical equipment" that consists of a heated humidifier and all of the necessary components required to deliver optimal humidity in a variety of applications. The MR850 is a new generation auto set dual servo controlled humidifier that offers invasive (trached) or noninvasive (mask or cannula) at the push of a button. In the invasive mode, the MR850 conditions gases to core temperature saturated and in the noninvasive mode, the MR850 conditions gases to match normal inspiratory levels. The MR850 is used for ventilation (invasive and noninvasive), respiratory assist (with and without back-up rate), positive airway pressure (noninvasive positive pressure ventilation), and continuous flow (humidified gas therapy and high flow oxygen therapy).

CMS HCPCS Workgroup Preliminary Decision: To use existing code E0562 humidifier, heated, used with positive airway pressure device.

Appropriate code assignment is made by the insurer in whose jurisdiction the claim is filed. For Medicare, if used with a ventilator, humidification is included in cost of ventilator rental and should not be separately billed. If used with CPAP, code E0562 should be used. No insurer identified a national program operating need to alter the existing code set to separately identify this item.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Meeting Agenda Item #9
June 23, 2005
HCPCS Request #05.128

Background/Discussion:
Joseph Lewarski of Inogen, Inc. submitted a request to establish a code for an oxygen concentrator, trade name: Inogen One Oxygen Concentrator. According to the requester, the Inogen One is a small, lightweight oxygen concentrator capable of fulfilling low flow prescriptions for oxygen while functioning as both a stationary and portable oxygen delivery device. It produces more then 90% pure oxygen for low flow oxygen therapy applications. Inogen One works on the principles of pressure-swing-adsorption, common to all oxygen concentrators. This oxygen production method draws and filters ambient air from the room by passing it through a filter system composed of a superior molecular sieve material. The sieve separates the oxygen from the nitrogen in the air, accumulates it and then pressurizes it in a reservoir. The oxygen-enriched gas is supplied to the patient via a standard nasal cannula in accordance with a physician prescription. Inogen One provides the prescribed oxygen to the patient at an equivalent rate of 1 to 5 liters per minute in increments of 0.5 liters per minute for a total of nine settings. Inogen is used by patients who are prescribed long term oxygen therapy (LTOT) outside of the acute care environment. Language proposed by applicant: EXXXX PORTABLE OXYGEN CONCENTRATOR USED AS A PORTABLE OXYGEN DELIVERY DEVICE, WEIGHING LESS THAN 10 POUNDS, CAPABLE OF DELIVERING 85% OR GREATER OXYGEN AND PROVIDING AT LEAST 2 HOURS OF REMOTE PORTABILITY AT A 2 LPM PRESCRIPTION EQUIVALENCY; INCLUDES CONCENTRATOR, CANNULA, TUBING AND AC/DC POWER CORD AND ADAPTER.

CMS HCPCS Workgroup Preliminary Decision: To use newly established code K0671 portable oxygen concentrator, rental (effective 4/1/2005).

Medicare Payment:
Portable oxygen equipment add-on fee and payment rule apply to this device.

Meeting Agenda Item #10
June 23, 2005
HCPCS Request #05.09

Background/Discussion:
Richard Weston of BlueSky Medical Group Inc. submitted a request to establish a code for powered suction pump, trade name: Versatile 1 Wound Vacuum System. According to the requester, Versatile is a portable suction device that can be powered by an internal battery pack, wall current or 12 volt input via optional cigarette lighter adaptor. The pump can be used for removal of surgical fluids, tissues, gases, bodily fluids or infected materials during surgery or from a patient's airway or respiratory support system. Versatile can also be used to create localized topical negative pressure when used with the Chariker-Jeter accessory kits to promote wound healing and drainage of fluids and infected materials from the wound into a disposable or reusable canister. Versatile consists of a medium sized housing that contains a vacuum pump and control system with a location for a fluid canister system. Accessories include a vehicle power adaptor and a Mobil stand. Versatile is indicated for promotion of wound healing or for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials from a patient's airway or respiratory support system either during surgery or at the patient's bedside.

CMS HCPCS Workgroup Preliminary Decision: Existing codes E1399 (durable medical equipment, miscellaneous) and E2402 (negative pressure wound therapy electrical pump, stationary or portable) are available for assignment by insurers.

Code assignment is made by the insurer in whose jurisdiction a claim would be filed. For Medicare, E1399 must be used to describe the item that is the subject of this request, as per existing policy, pending the outcome of a technology assessment. For the private insurance sector, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
Deferred for technology assessment

Meeting Agenda Item #11
June 23, 2005
HCPCS Request #05.131

Background/Discussion:
David Hintzman of Bodypoint, Inc. submitted a request to establish a code for a dynamic pelvic stabilization device, trade name: Bodypoint Hip Grip. According to the requester, Bodypoint is a pelvic stabilization device equipped with variable resistance springs that assists the wheelchair user to maintain pelvic stability while allowing functional pelvic movements. Hip Grip incorporates rear, front, and side support of the pelvis in an adjustable unit, which allows the pelvis to pivot forward about the hip joint within a specified range. It reduces undesired pelvic movement and provides variable resistance to bring the pelvis back into its neutral posture after allowing movement. The combination of pelvic positioning and dynamic pelvic movement improves functional activities and enhances sitting posture. Bodypoint is used primarily by those patients with cerebral palsy and spinal cord injury. The pivot mechanism of Bodypoint incorporates an elastic resistance band that allows forward pelvic movement within range depending on the person's flexibility, balance and feedback. The quick release wheelchair attachment hardware combination assures the greatest compatibility with a wide range of wheelchairs and the ability to remove it for folding the wheelchair when necessary.

CMS HCPCS Workgroup Preliminary Decision: To use existing code E0978 wheelchair accessory, positioning belt/safety belt/pelvic strap, each.

Existing code E0978 adequately describes a category for pelvic positioning devices that perform a function similar to the Hip Grip device described in your application. Sufficient evidence has not been provided to demonstrate a distinction in terms of stability or dynamic stability, as a result of the use of this product compared with other items included in E0978. No insurer identified a national program operating need to alter the existing code set to uniquely identify the Bodypoint Hip Grip.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Meeting Agenda Item #12
June 23, 2005
HCPCS Request #05.134

Background/Discussion:
David Boninger of Three Rivers submitted a request to establish a code for wheelchair propulsion and braking assembly, trade name: Natural-Fit™. According to the requester, Natural Fit is a wheelchair propulsion and braking assembly ergonomically designed to fit the hand and reduce stress on the hands, wrists, and arms when propelling a manual wheelchair, thereby treating the pain associated with Carpal Tunnel Syndrome (CTS). The Natural Fit is an assembly because it has two separately coated components, a smooth oval surface for the palm of the hand and a higher friction contoured slot for the thumb. The assembly of these two components is designed to create an ergonomic grip for the hand and to provide separate surfaces for propulsion and braking. The contoured trough provides a surface area between the rim and tire to increase the contact area for the thumb to apply propulsion forces. By adding the trough, the gap between the tire and standard handrims is eliminated which enhances safety (e.g., fingers can no longer get caught in the gap). The ergonomic grip provided by the combination of the contoured trough and the oval component of the Natural Fit reduces finger tip loading, pinch gripping, and excessive activation of the finger flexors during wheelchair propulsion.

CMS HCPCS Workgroup Preliminary Decision: Existing code E2205 (manual wheelchair accessory, handrim without projections, any type, replacement only, each), is available for use by all payers.

Existing code E2205, adequately describes a category of wheelchair handrims which perform a function similar to the Natural Fit product. Testimonials and summaries of articles provided by the applicant do not demonstrate a significant therapeutic distinction between the category of items described by E2205 and the item in the coding request. Code assignment is made by the insurer in whose jurisdiction a claim would be filed. For Medicare, E2205 is the appropriate code, and it is not appropriate to use K0108 or other miscellaneous codes to identify the item that is the subject of this request. For private insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Meeting Agenda Item #13
June 23, 2005
HCPCS Request #05.135

Background/Discussion:
Robert Fulton III of Glance Wheels, LLC submitted a request to establish a unique code to differentiate rear wheels for manual wheelchairs that are maintenance free, extended life, high durability from other rear wheels currently coded at K0069, K0070 or K0108. According to the applicant, Glance wheels are no maintenance, high durability, high strength aircraft quality aluminum rear wheels. These wheels are intended for long term and active use. Glance wheels are intended to never be replaced and can have an extended and continuous "life". Thus Glance Wheels are resistant to usual "wear and tear" common with active disabled users of manual wheelchairs. These wheels do not require "spoke tuning" or "truing" of the wheel rim. Glance wheels are used by paraplegics, quadriplegics, amputees and other individuals using a manual wheelchair for over 4 hours per day with a continued wheelchair use to exceed one year. Current codes do not specify a high endurance, long life, no maintenance product for active users of manual wheelchairs.

CMS HCPCS Workgroup Preliminary Decision: Existing codes K0069 (rear wheel assembly, complete, with solid tire, spokes or molded, each) and K0070 (rear wheel assembly, complete, with pneumatic tires, spokes or molded, each), are available for use by all payers, and adequately describe rear wheel assemblies (solid or pneumatic).

Use existing code K0069 or K0070 as appropriate,based on whether the tires are solid or pneumatic. Use of K0108 (wheelchair component or accessory, not otherwise specified) is not appropriate. No insurer identified a national program operating need to distinguish wheels products based on degree of durability. Products either meet durable medical equipment standards or they don't. This product does not offer significant therapeutic distinctions from other wheels, and it performs a function for the patient similar to the function of other wheels.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Meeting Agenda Item #14
June 23, 2005
HCPCS Request #05.136

Background/Discussion:
Greg Howard of Independence Technology, LLC submitted a request to establish a code for a mobility system, trade name: Independence iBot 3000 Mobility System. According to the requester, iBot is a sophisticated mobility system with patented iBalance technology enabling users to climb and descend stairs, navigate surfaces, ascend curbs and balance the seat user at a "standing" eye-level height. iBot is an integrated combination of mechanical, electronic, sensor, and software components that is customized to the user's size, weight and center of gravity. The iBalance technology is comprised of six solid-state gyroscopes, three tilt sensors, three computer processor systems and multiple sensors. This technology is integrated with a cluster of two, interconnected, 12-inch wheels on each side of the device as well as two smaller caster wheels in the front of the device. The device automatically adjusts wheel and/or frame position in reaction to changes in pitch, wheel velocity, wheel position, seat height and other parameters based on a complex series of computerized sensors and software algorithms. iBot is powered by two, 72-volt rechargeable nickel-cadium batteries that can power the device all day on a single charge depending on usage.

CMS HCPCS Workgroup Preliminary Decision: Use existing K0011 STANDARD - WEIGHT FRAME MOTORIZED/POWER WHEELCHAIR WITH PROGRAMMABLE CONTROL PARAMETERS FOR SPEED ADJUSTMENT, TREMOR DAMPENING, ACCELERATION CONTROL, AND BRAKING

Existing code K0011 adequately describes a category of motorized wheelchairs that perform a function similar to the chair component of the iBOT.

The entire power wheelchair and accessory code series has recently been revised after considerable input and cooperation from stakeholders. No insurer identified a national program operating need to identify the power chair component of the iBOT, combined with separately codeable accessories, as a distinct chair type. Code assignment for the chair and accessories are made by the insurer in whose jurisdiction a claim is filed. For Medicare, use Code K0011 STANDARD - WEIGHT FRAME MOTORIZED/POWER WHEELCHAIR WITH PROGRAMMABLE CONTROL PARAMETERS FOR SPEED ADJUSTMENT, TREMOR DAMPENING, ACCELERATION CONTROL, AND BRAKING with the KF modifier ITEM DESIGNATED BY FDA AS CLASS III DEVICE to describe the power chair component of the iBOT; use code E2300 POWER WHEELCHAIR ACCESSORY, POWER SEAT ELEVATION SYSTEM to describe the elevating feature; and use code A9270 NON-COVERED ITEM OR SERVICE to describe the stair climbing feature, which is not covered by Medicare. For coding guidance for

power wheelchair accessories for private insurance systems, contact the individual private insurance contractor. For Medicaid systems, contact the Medicaid agency in the state in which a claim would be filed.

Medicare Payment:

Fee schedule and payment rules associated with existing code apply to this device.

Meeting Agenda Item #15
June 23, 2005
HCPCS Request #05.05 A&B

Background/Discussion:
Jessica Lurz of Dynasplint Systems, Inc. submitted a request to A) establish a modifier to distinguish between extension and flexion dynamic adjustable joint stretch devices and B) establish a code to identify a dynamic adjustable metacarpo-phalangeal (MCP) joint stretch device. According to the requester, Dynasplint systems are joint stretch devices that provide a low-load prolonged-duration stretch for shortened connective tissue, thus relieving joint stiffness and regaining lost range of motion caused by injury, surgery, trauma or disease. Each unit is made of stainless steel that will withstand an extensive refurbishment process and soft interface material that comes in contact with the body. These MCP units are designed to be worn at rest or while sleeping for 8-10 hours to give patients several hours of therapy while sleeping. Each unit comes complete with a tensioning tool to either increase of decrease the force applied to the joint, according to the patient's comfort.

CMS HCPCS Workgroup Preliminary Decision: To use existing code E1825 (dynamic adjustable finger extension/flexion device, includes soft interface material) for both A & B.

Existing code E1825 includes flexion and extension, and adequately identifies a category of devices that perform a function similar to the devices described in this application. Separation of flexion and extension could result in billing confusion or inadvertent duplicate billing. No insurer identified a national program operating need to alter the existing HCPCS code set to separate flexion and extension or to isolate finger joints.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Meeting Agenda Item #16
June 23, 2005
HCPCS Request #05.26

Background/Discussion:
Frank Joutras of Inverse Technology Corporation submitted a request to establish a code for a functional neuromuscular control device, trade name: Protonics. Requester claims that instruction to code E1810 is inappropriate because the product is not being used for what E1810 was originally intended; Protonics is not a spring-loaded device or intended for non-functional use after surgery. Requester claims this is causing confusion to third party payers. Therefore requester is seeking a new E code. According to the requester, Protonics is an external limb component that is added to, or part of an orthosis. This device is used only while the patient is functioning to control neuromuscular activation of certain muscle groups during motion allowing the device to influence joint kinematics and contact areas associated with the pelvis, femur and patella resulting in increased function and decreased pain during activities. Protonics uses a patented and unique form of functional resistance to influence certain neuromuscular activity only while the patient is walking or performing functional movements. Usage of the device needed on a daily basis is patient dependent, but most patients will need to use the device extensively over the first few months, and then periodically based on their activity level.

CMS HCPCS Workgroup Preliminary Decision: Existing code E1810 dynamic adjustable knee extension/flexion device, includes soft interface material is available for assignment by insurers and adequately describes the item that is the subject of this request.

Items previously coded under L1885 (knee orthosis, single or double upright, thigh and calf, with functional active resistance control, prefabricated, includes fitting and adjustment), were crosswalked to new code E1810 (dynamic adjustable knee extension/flexion device, includes soft interface material), at the time L1885 was discontinued. The item that is the subject of this request was a predicate product for the original establishment of L1885. It is appropriately crosswalked to and adequately described by E1810, and performs a similar function to products coded at E1810. There is no significant therapeutic distinction between this item and other products identified by code E1810. All items are used as physical therapy equipment and not separated as orthotics. These products can no longer be purchased as rental items. This product is used to build up muscle, not reduce contracture, and functions like a dynamic splint. Code assignment is made by the insurer in whose jurisdiction a claim would be filed. For Medicare, use existing code E1810. For private insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Meeting Agenda Item #17
June 23, 2005
HCPCS Request #05.127

Background/Discussion:
Lance Matthews of CANADALEG Inc. submitted a request for an "L" code for a mobility rehabilitation device, Trade Name: IWALKFree. According to the requester, the IWALKFree is a rehabilitation device that can also be used as a temporary prosthetic, orthotic or brace. It replaces a missing lower leg or a lower leg that has been injured and is in need of rehabilitation. It allows weight to be transmitted through the flexed knee resulting in no weight being borne by the tibia, ankle, or foot. The device is made of a fiber reinforced injection molded knee tray with adjustable fitting positions that is attached to an extruded single piece aluminum shaft. Hypoallergenic foam is used on the knee tray, which allows bare skin and wounds to be attached directly to the tray. A three-point attachment system ensures stability. It is set off center, with rounded rubber foot, which replicates normal walking motion.

CMS HCPCS Workgroup Preliminary Decision: To use existing code E0118 crutch substitute, lower leg platform, with or without wheels, each.

The product that is the subject of this request is, in fact, one of the predicate products considered in originating code E0118. The product is not an orthotic or a prosthetic. Specific inquiries regarding processing Medicare claims or "down-coding", as raised in your application, should be submitted directly to the Regional DMERC in whose jurisdiction the claim was filed.

Medicare Payment:
Coverage and payment based on contractor discretion.

Meeting Agenda Item #18
June 23, 2005
HCPCS Request #05.129 A&B

Background/Discussion:
James Boswell of King & Spalding LLP submitted a request to A) either suggest that the Statistical Analysis Durable Medical Equipment Regional Carriers (SADMERC) reassign the Nasal Pap Freestyle Cushions from A7033 REPLACEMENT PILLOWS FOR NASAL APPLICATION DEVICE, PAIR to A7032 REPLACEMENT CUSHION FOR NASAL APPLICATION DEVICE, EACH; or establish a new code for the Nasal Pap freestyle Cushions and B) to either suggest that the SADMERC reassign the Nasal-Aire II Cushion from A9999 to A7032 or to establish a new code for the Nasal-Aire II Cushion. According to the requester, Nasal Pap cushions are rough cylindrical cushions made with a soft medical grade silicone. These cushions are used in conjunction with a CPAP device for the treatment of patients with obstructive sleep apnea and related disorders. A pair of the Nasal Pap cushions is inserted into each nasal cavity and connected to tubing and a swivel connection and then to the CPAP positive air pressure machine. Nasal Pap cushions channel air with a laminar flow from the CPAP machine to the patient's nose, providing patients with breathing assistance. Nasal Aire II consists of a connected pair of cylindrical nasal inserts to be used in conjunction with a CPAP device for the treatment of patients with obstructive sleep apnea and related disorders. The cushion's nasal inserts are inserted into each nasal cavity and forms an air seal with each nasal cavity. Nasal Aire II cushion channels air with a luminar flow from the CPAP machine to the patient's nose, providing breathing assistance.

CMS HCPCS Workgroup Preliminary Decision:
#05.29A
To use existing code A7033 replacement pillows for nasal application device pair.

Existing code A7033 adequately describes the item that is the subject of your request (nasal PAP Freestyle Cushions), therefore a new code is not necessary to describe this product and would be duplicative of existing code A7033. The product distinctions described in your application are not significant therapeutic distinctions from other items in the same code category, and Nasal PAP Freestyle cushions function similar to other items in the same category.

#05.29B
To use existing code A7032 replacement cushion for nasal application device, each.

Existing code A7032 adequately describes the item that is the subject of your request (Nasal Air II Cushion), therefore a new code is not necessary to describe this product and would be duplicative of existing code A7032. The product distinctions described in your application are not significant therapeutic distinctions from other items in the same code category, and Nasal Air II cushions function similar to other items in the same category.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to these devices.

Meeting Agenda Item #19
June 23, 2005
HCPCS Request #05.130

Background/Discussion:
James Koeneman of Kinetic Muscles, Inc. submitted a request to establish a code for a repetitive active motion device, trade name: Hand Mentor. According to the requester, Hand Mentor is a device designed primarily for rehabilitation therapy for those having suffered a stroke. This device is primarily used for Active-Assist stroke therapy where the patient is encouraged to move as much as possible and then the device completes the motion for the patient. An artificial pneumatic muscle provides the coordinated motion. In addition, the device measures the electrical activity of selected muscle groups through surface electromyographic electrodes and the resistance of spastic muscles and feeds back this information to the patient to encourage maximum effort.

CMS HCPCS Workgroup Preliminary Decision: To use existing code E1399 (durable medical equipment, miscellaneous).

To revise code E0935 to read (continuous passive motion exercise device for use on knee only), to clarify that this product is not included in the E9035 code category.

No insurer identified a national program operating need to alter the existing code set to identify this item. Your reported sales volume was insufficient to support your request for a revision to the national codes (28 units sold since market introduction in March 2003). There must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity for non-drug products, so that the adding of a new or modified code enhances the efficiency of the system and justifies the administrative burden of adding or modifying a code. CMS invites the applicant to reapply when sales volume increases substantially. HCPCS code E0935 has been revised to clarify that the Hand Mentor is *not* included in the E0935 code category. The Hand Mentor does not fit the criteria for any Medicare Benefit Category. Also, it is not covered under the National Coverage decision for passive motion exercise for the knee only, for which E0935 was developed. For Medicare, the Hand Mentor should be coded using E1399. For coding guidance for private insurance systems, contact the individual insurance contractor. For Medicaid systems, contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment: This device is not covered.

Meeting Agenda Item #20
June 23, 2005
HCPCS Request #05.132A-D

Background/Discussion:

#05.132A

Jonathan Cabral of Bionicare Medical Technologies, Inc. submitted a request to establish a code for a knee signal applicator used with the BioniCare Stimulator, Model BIO-1000. According to the requester, the knee signal applicator is a "noninvasive arthritis treatment device that is worn outside of the body on the joint requiring treatment". BioniCare Signal Generator delivers a specific electrical output to contact elements that are held in place by this knee signal applicator system that accurately positions and applies a special treatment contact element to the surface of the knee and a special return contact element to the surface of the thigh. Bionicare's knee signal applicator is worn on the knee when an adjunctive therapy is used to reduce the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the physician's global evaluation. The knee signal applicator is applied using a fastener system of Velcro materials, a support belt, and suspension strap. Both right and left knee applicators and support belts are manufactured in three sizes, small, medium, and large. The knee signal applicator is designed for use eight to ten hours daily for periods up to two years. It can survive up to 350 hand-washing cycles. Code description recommended by applicant: E07XX SIGNAL APPLICATOR DEVICE, KNEE; FOR USE WITH ARTHRITIS TREATMENT DEVICE.

#05.132B

Jonathan Cabral of Bionicare Medical Technologies, Inc. submitted a request to establish a code for a replacement battery use with the BioniCare Stimulator, Model BIO-1000. According to the requester, the battery is part of BioniCare's Stimulator, Model BIO-1000 System, which is a noninvasive arthritis treatment device that is worn outside of the body on the joint requiring treatment. The rechargeable battery is required for continued operation of the electronic signal generator. Battery life is dependent on patient use patterns. Under normal use conditions, it is anticipated that a replacement battery will be required after 12 months. Code description recommended by applicant: A46XX REPLACEMENT BATTERY FOR ARTHRITIS TREATMENT DEVICE ELECTRONIC SIGNAL GENERATOR, EACH

#05.132C

Jonathan Cabral of Bionicare Medical Technologies, Inc. submitted a request to establish a code for replacement supplies used with the BioniCare Stimulator, Model BIO-1000. According to the requester, the replacement supplies are part of the BioniCare Stimulator Model BIO-1000 that is worn outside of the body on the joint requiring treatment. This code request is specific to report a kit of replacement supplies, including 2 contact elements/electrodes and 6 (8.5oz) supplementary gel tubes. The quantity of supplies is expected to last 2-3 months under typical product use conditions for one signal applicator. A second set of supplies would be required if a patient were using two signal applicators. Code description recommended by applicant: A4xxx ARTHRITIS TREATMENT DEVICE SUPPLY KIT, EACH.

#05.132D
Jonathan Cabral of Bionicare Medical Technologies, Inc. has submitted a request to establish a code for an arthritis treatment device, Trade Name: BioniCare® Stimulator, Model BIO-1000™. According to the requestor, the BioniCare Stimulator, Model BIO-1000™ is a non-invasive arthritis treatment device that is worn outside of the body on the joint requiring treatment. It is indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the physician's global evaluation and an adjunctive therapy in reducing the level of pain and stiffness from rheumatoid arthritis of the hand. The device is worn for 8 +/- 2 hours every day, usually at night but can be worn during the day. Clinical experience indicates a range of use from one to 51 months. The average length of use in a long term study was 11 months. Description recommended by applicant: E07xx ARTHRITIS TREATMENT DEVICE, ELECTRICAL, NONINVASIVE.

CMS HCPCS Workgroup Preliminary Decision: To establish a new "E" code:

E???? Transcutaneous electrical joint stimulation device system, includes all accessories.

This new code would be used to identify the system, including the stimulator, knee signal applicator, batteries and related supplies.

Medicare Payment:
This item falls under the capped rental DME payment category. Fee schedule amounts are established by the DMERCs in accordance with CMS gap-filling instructions.

Meeting Agenda Item #21
June 23, 2005
HCPCS Request #05.167

Background/Discussion:
Kirk MacKenzie of Snug Seat has submitted a request to establish 2 codes: 1) pediatric dynamic stander and three way stander, Trade Name: Pediatric Dynamic Stander – Rabbit Mobile Stander (Snug Seat) and 2) Pediatric Three-Way Stander, angle adjustable, permits prone, supine, and vertical standing – Gazelle P/S Standing Frame (Snug Seat). According to the requestor, a pediatric dynamic stander is a device that places a child who cannot stand independently, in an upright or prone position and allows him to self-propel. The stander angle accommodates a range from upright to > 20 degrees prone. It differs from a basic simple standing frame in that the simple standing frame serves one single purpose – upright standing, prone standing, or supine standing, while the pediatric dynamic stander is a standing device that provides the child with independent mobility.

CMS HCPCS Workgroup Preliminary Decision:
1) To use code E0638.

2) To revise E0638 which currently reads standing frame system, any size, with or without wheels, to instead read: standing frame system, any size, any type, with or without wheels.

E0638 adequately describes standing frames. The descriptor will be revised to add the words "any type", to clarify that the code category is intended to describe the variety of devices on the market. No insurer representative of the CMS HCPS Workgroup identified a national program operating need to alter existing code set to distinguish dynamic and 3-way standers.

Medicare Payment:
Standing frames and standing tables do not meet the definition of DME.

Meeting Agenda Item #22
June 23 2005
HCPCS Request #05.92

Background/Discussion:
Sara Christine Oxton of Otto Bock Health Care has submitted a request to establish a code for a wheelchair cushion with phase change materials (PCMs) for skin protection through temperature control, Trade Name: ComforT Cushion. According to the requestor, the ComforT is a wheelchair cushion made with phase change materials for skin protection. The requestor claims that lab studies prove that the ComforT absorbs enough heat to keep the seat interface temperature 10-degrees cooler on average than standard skin protection systems. This cooler temperature blocks moisture formation, which is a key contributor to skin breakdown and pressure sore formation. The PCMs also serve to slow metabolic activity in the seat interface area. The ComforT is used by people whose primary mobility device is a wheelchair. Indications for use include high need for skin protection, or strong propensity toward heat build up while sitting.

CMS HCPCS Workgroup Preliminary Decision: To use existing code K0108 wheelchair component or accessory, not otherwise specified.

The SADMERC is in the process of developing testing standards for adjustable cushions. New codes may be established when the testing criteria is finalized and released. Such codes if established would be available for potential use by all payers. In the meantime, K0108 should be used to identify this item. There is no medical evidence to support a therapeutic distinction based on phase change materials or other heat mitigation factors. No payer has identified a national program operating need to alter the existing code set at this time, to distinguish cushions based on temperature control factors.

Medicare Payment:
Local fee schedule amounts are established by DMERCs for items covered under codes for items not otherwise specified.

Meeting Agenda Item #23
June 23, 2005
HCPCS Request #05.91 A-C

Background/Discussion:

Tom Walsh of Advanced Bionics Corporation submitted a request to: A) Establish a code for an implantable neurostimulator pulse generator, trade name: Precision, B) Revise code E0756 to read: IMPLANTABLE NEUROSTIMULATOR PULSE GENERATOR WITH NON-RECHARGEABLE BATTERY, currently reads: IMPLANTABLE NEUROSTIMULATOR PULSE GENERATOR and C) Establish a code for an implantable neurostimulator charging system. According to the requester, Precision rechargeable IPG is an implantable neurostimulator pulse generator that is part of a spinal cord stimulation system used to provide electrical stimulation of the spinal cord for the management of chronic, intractable pain. Precision is designed to deliver current to implanted lead(s) and replace pain sensations with paresthesia, or a cool tingling sensation. It aids in the management of chronic intractable pain of the trunk and/or limbs associated with failed back surgery syndrome, intractable low back pain and leg pain. The Precision is a new generation of neurostimulator that represents an improvement over existing RF generators and non-rechargeable IPGs by providing a rechargeable battery that dramatically increases lifespan of the neurostimulator in clinical practice while allowing for higher power stimulation settings and neurostimulation through multiple independent current sources. According to the requester, the Precision IPG charging system is part of a spinal cord stimulation system used to provide electrical stimulation of the spinal cord for the management of chronic, intractable pain. This external patient charging system is used by the patient to recharge the battery in the Precision rechargeable IPG. The charging system contains a charger with a lithium battery that is recharged in a base station. The charger converts electrical energy to radio frequency energy. The generator converts the RF energy to electrical energy, which recharges its internal battery.

CMS HCPCS Workgroup Preliminary Decision:

#05.91A & B

To use existing code C1767 Generator, neurostimulator (implantable) or E0756 Implantable neurostimulator pulse generator.

Existing codes, C1767 or E0756, adequately describe a category of items which are functionally similar to the item in this coding request. Initial implantation of device should include charging system if provided. There are no significant therapeutic distinctions between the category of items described in this code and the items in the coding request. There is currently no national program operating need to alter the existing code set to differentiate between rechargeable and non-rechargeable systems.

#05.91C

To establish a new "E" code.

E???? External recharging system for implanted neurostimulator, replacement only

Use E???? to identify external recharging system for only for replacement.

Medicare Payment:

E???? is an accessory for an implanted prosthetic device (E0756). Payment for E0756 includes payment for all accessories. Payment for replacement of accessories can be made when they are lost, stolen, irreparably damaged, or when the item has exceeded its reasonable usefule lifetime. Fee schedule amounts for code E???? will be established by CMS in accordance with gap-filling policies.

Meeting Agenda Item #24
June 23, 2005
HCPCS Request #05.133

Background/Discussion:
Patty Curoe of Medtronic Diabetes submitted a request to establish a code for The Pathway™ Program, separately purchased software that allows patients to upgrade their insulin pumps, rather than purchasing an entirely new pump. Applicant suggests the following language for the requested new code: Exxxx SOFTWARE UPGRADE, EXTERNAL AMBULATORY INFUSION PUMP. According to the requester, Paradigm is software that is used to upgrade existing insulin pumps. This accelerates patient access to ongoing clinical advancements, without incurring repeated pump replacement costs or long delays in technology advances during pump warranty periods. Pathway can be used to update earlier versions of insulin pumps to obtain the calculator feature. In addition, other innovations such as radio frequency transmitted blood glucose values from meters to pumps are available without incurring the full costs of a replacement pump. Future advances that are expected to be a part of Pathway include an upgrade to accept and display real time glucose readings from an external glucose sensor and transmitter.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a code.

This item is considered in-warranty software, and it is not - in and of itself - primarily medical in nature. Code assignment is made by the insurer in whose jurisdiction a claim would be filed. For Medicare, A9270 NON-COVERED ITEM OR SERVICE is the appropriate code. For coding guidance for private insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed. No insurer identified a national program operating need for a code to identify this item.

Medicare Payment: This device is not covered.